K041504

AUG - 6 2004

Section 1

510(k) SUMMARY

Date Prepared: June 4, 2004

Submitter:
Haemacure Corporation
2 North Tamiami Trail
Sarasota, FL 342020

Haemacure Contact: Dr. Christian Hours
(888) 621-8076 ext. 28

Submission Contact: Elaine Whitmore
SciVance Consulting
(941) 350-2631

Device Name:
HemaMyst Surgical Applicator System

Common/Usual/Classification Name:
Syringe, Piston

Predicate Device(s):
Haemacure HemaMyst Surgical Applicator System
510(k) No. K994023
Haemacure Corporation

Tissomat and Spray Set
510(k) No. K981089
Baxter Healthcare Corporation

Device Description:

The HemaMyst Surgical Applicator System is a sterile, single-use device consisting of a spray head that attaches by Luer connectors to currently available dual syringe applicators, and is coupled to an air regulator base unit by means of a sterile filtered air line. The HemaMyst Surgical Applicator System allows simultaneous delivery, by spraying, of the two components of fibrin sealant to the treatment site.

The change from the predicate Haemacure HemaMyst Surgical Applicator System device is the indication for application of the two separate components of HEMASEEL APR

Fibrin Sealant or Tisseel VH Fibrin Sealant. (*Note*: HEMASEEL APR and Tisseel VH fibrin sealants are identical products.) The HemaMyst Surgical Applicator System is currently indicated for the application of two non-homogeneous fluids or solutions to the treatment site, through the provisions of 510(k) No. K994023.

Like the Tissomat and Spray Set, the HemaMyst Surgical Applicator System is attached to a currently available dual syringe applicator, and separately delivers the two separate fibrin sealant components from the syringes to a spray tip for application to the treatment site. Like the Tissomat and Spray Set, the HemaMyst Surgical Applicator System uses compressed gas to enhance component mixing and spraying.
NOTE: The HemaMyst spray head should be used only with a dual syringe applicator, such as the Duploject Dual Syringe Applicator, that has been determined by direct performance testing to be compatible both with the HemaMyst spray head and with the application of HEMASEEL APR or Tisseel VH fibrin sealant.

Functionality testing shows that the HemaMyst Surgical Applicator System is substantially equivalent to the Tissomat and Spray Set in the delivery of HEMASEEL APR or Tisseel VH fibrin sealant.

Intended Use:

The HemaMyst Surgical Applicator System is indicated for the simultaneous application of the two components of HEMASEEL APR Fibrin Sealant or Tisseel VH Fibrin Sealant to the treatment site.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 6 2004

Haemacure Corporation
C/O Dr. Elaine Whitmore
SciVance Consulting
7113 River Club Boulevard
Bradenton, Florida 34202

Re: K041504
Trade/Device Name: HemaMyst Surgical Applicator System
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: June 4, 2004
Received: June 7, 2004

Dear Dr. Whitmore:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

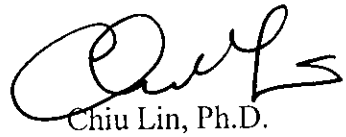
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Aso, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K041504**

Device Name: **HemaMyst Surgical Applicator System**

Indications For Use:

The HemaMyst Surgical Applicator System is indicated for the simultaneous application of the two components of HEMASEEL APR Fibrin Sealant or Tisseel VH Fibrin Sealant to the treatment site.

Prescription Use ____X___ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K041504